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PRE-APPEAL BRIEF REQUEST FOR REVIEW		Docket Number 06530.0276-00000
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Signature _____		Filed September 21, 2001
Typed or printed name _____		First Named Inventor Marc O. SCHURR
		Art Unit 3773
		Examiner Darwin P. Erezo

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a Notice of Appeal.

The review is requested for the reason(s) stated on the attached sheet(s).

Note: No more than five (5) pages may be provided.

I am the

 applicant/inventor.

Signature

 assignee of record of the entire interest.

See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.

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 attorney or agent acting under 37 CFR 1.34.

Registration number if acting under 37 CFR 1.34 _____

March 3, 2009

Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required.
Submit multiple forms if more than one signature is required, see below*.

 *Total of 1 forms are submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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PATENT
Customer No. 22,852
Attorney Docket No. 06530.0276-00000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
Marc O. SCHURR et al.) Group Art Unit: 3773
Application No.: 09/957,451) Examiner: Darwin P. Erezo
Filed: September 21, 2001) Confirmation No.: 2507
For: METHODS AND DEVICES FOR)
FOLDING AND SECURING TISSUE)

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Applicant requests a pre-appeal brief review of the rejections set forth in the final Office Action mailed September 9, 2008 ("Office Action").¹

I. The Rejection of the Claims Under 35 U.S.C. § 103(a) is Improper

Independent claims 1, 120, 135, and 148 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 3,604,425 to Le Roy ("Le Roy") in view of U.S. Patent No. 5,620,452 to Yoon ("Yoon"). However, the proposed modifications of the clip of *Le Roy* are improper because, as described below, they counter the express teachings of *Le Roy*, frustrate the intended purpose of the clip of *Le Roy*, and change its principle of operation.

A. There is no motivation to modify the clip of *Le Roy* to be comprised of bioabsorbable material capable of disintegrating in a body

Independent claim 1 recites a device for securing a fold of tissue in a medical procedure including, among other things, "a first arm [and] a second arm . . . wherein the first and second arms are comprised of a bioabsorbable material such that the first and second arms are capable of disintegrating in a body."

Le Roy discloses a clip 10 including leg sections 24 "for use in clamping wound flaps to prevent the flow of blood from severed arteries, capillaries and the like." (*Le Roy*, col. 1, ll. 11-13; col. 2, ll. 47-50; Figs. 1-5). The clip 10 of *Le Roy* includes projections 18 that are squeezed together using an applicator tool 14 or by hand to allow application and removal of the clip 10. (*Le Roy*, col. 2, ll. 64-69; and Fig. 1).

¹ The Amendment After Final filed January 9, 2009, canceling claim 4 has been entered, and therefore the rejection of claim 4 under 35 U.S.C. § 112, second paragraph, is now moot.

The Office Action acknowledges that *Le Roy* does not disclose that “the first and second arms are comprised of a bioabsorbable material such that the first and second arms are capable of disintegrating in a body,” as recited in claim 1. (Office Action, p. 5, ll. 1-2). However, the Office Action contends that *Yoon* discloses this feature and that “it would have been obvious . . . to manufacture the device of *Le Roy* with a bioabsorbable material since it would allow the clip to dissolve in the body without requiring . . . surgery for removal.” (Office Action, p. 5, ll. 3-7).

However, there is no motivation to modify the clip 10 of *Le Roy* to be comprised of bioabsorbable material, as proposed by the Office Action. *Le Roy* states that the “[c]lip 10 is particularly effective with scalp and back wounds, and . . . abdominal or long flap wounds as may be necessary in extremity work.” (*Le Roy*, col. 3, ll. 21-24). Therefore, *Le Roy* discloses using the clip 10 for external wounds on the patient’s skin, not in the patient’s body. Accordingly, since the clip 10 of *Le Roy* is for external purposes, there is no motivation to modify the clip 10 of *Le Roy* to be made of bioabsorbable material capable of disintegrating in a body.

The Advisory Action mailed December 5, 2008 (“1st Advisory Action”) relied on a portion of *Le Roy* that states that the clip can be located if “lost” within the operative site. (1st Advisory Action, p. 2, ll. 7-8; *Le Roy*, col. 3, ll. 10-12). The 1st Advisory Action alleged that, since the clip of *Le Roy* may be lost within the body, the clip may be used internally, and therefore, it would be obvious to form the clip of bioabsorbable material. (1st Advisory Action, p. 2, ll. 7-10). The 1st Advisory Action also alleged that “[a] clip used exclusively in external surfaces of the patient will not require [] disclosure” of the clip being “lost” within the operative site. (1st Advisory Action, p. 2, l. 8). However, *Le Roy* merely states that the clip may be introduced internally when it is lost by accident. A clip used externally may be lost if the clip enters by accident through an external wound. Therefore, this portion of *Le Roy* does not disclose or suggest using the clip internally. Rather, this portion of *Le Roy* further shows that the clip is not intended to be inside the patient’s body and is intended to be located so that it may be removed from the patient’s body. *Le Roy* teaches away from using the clip internally and from allowing the clip to remain inside the patient’s body. It is improper to combine references where the references teach away from their combination. M.P.E.P. § 2145(X)(D). Therefore, there is no motivation to modify the clip of *Le Roy* to be comprised of bioabsorbable material capable of disintegrating in a body.

Furthermore, *Le Roy* states that the clip 10 “can be easily and rapidly removed either with applicator 14 or by hand” and that projections 18 on the clip 10 allow the clip 10 to be removed manually. (*Le Roy*, col. 2, ll. 64-67). The clip 10 of *Le Roy* is specifically designed to be “easily and rapidly removed . . . off the wound flap 16 without noticeable damage to the tissue.” (*Le Roy*, col. 2, ll. 68-69). Therefore, since the clip 10 of *Le Roy* is specifically

designed to be easily and rapidly removable, there is no motivation to modify the clip 10 to allow it to disintegrate in the patient's body, i.e., so that the clip 10 cannot be removed by, for example, a tool or hand. For this additional reason, *Le Roy* teaches away from forming the clip of bioabsorbable material capable of disintegrating in a body.

The Advisory Action mailed February 6, 2009 ("the 2nd Advisory Action"), did not add to the arguments provided in the 1st Advisory Action, except to say that "hemostatic clips are well known to be used internally for closing internal wounds, as evidenced by [U.S. Patent No.] 4,246,903 to Larkin" ("*Larkin*"). *Larkin* discloses a hemostatic clip that may be applied to "a blood vessel or other internal tubular member." (*Larkin*, col. 1, ll. 8-10). However, *Larkin* does not alter the fact that *Le Roy* teaches away from using the clip internally and from forming the clip of bioabsorbable material capable of disintegrating in a body, as noted above.

Independent claims 120, 135, and 148, although of different scope, each includes elements corresponding to those of claim 1 discussed above and are patentable for at least the same reasons. U.S. Patent No. 3,032,039 to *Beaty* ("*Beaty*") was additionally applied against several claims that depend from one of these independent claims. However, *Beaty* does not cure the deficiencies of *Le Roy* and *Yoon* noted above, nor was it cited for such disclosure.

The Advisory Actions also did not address any of the following arguments provided in the Amendments After Final filed November 5, 2008, and January 9, 2009.

B. Modifying *Le Roy* based on *Beaty* is improper

Dependent claims 132, 145, 155, 173, 175, 177, and 179 were rejected based on *Le Roy*, *Yoon*, and *Beaty*. However, modifying *Le Roy* based on *Beaty*, as proposed by the Office Action, is improper for at least the following reasons.

The Office Action acknowledges that *Le Roy* does not disclose or suggest the "gripping tab located at the distal end of one of the first and second arms" recited in claims 132, 145, and 155 or the "crook for providing a surface to push against to bring the arms closer together during insertion" recited in claims 173, 175, 177, and 179. (Office Action, p. 7, ll. 6-7). The Office Action contends that "it would have been obvious . . . to modify the device of *Le Roy* to have the tabs be located on the distal end . . . because such arrangement is well known in the art [or because] the arrangement taught by *Beaty* is an equivalent structure." (Office Action, p. 7, ll. 8-18). However, one of ordinary skill in the art would not have made the substitution proposed by the Office Action because the proposed substitution would render the clip of *Le Roy* unsatisfactory for its intended purpose and would change its principle of operation. It has long been held that a proposed modification of the prior art cannot render the prior art "unsatisfactory for its intended purpose" or "change its principle of operation." M.P.E.P. § 2143.01(V)-(VI).

Le Roy provides the projections 18 at the proximal end of the device to facilitate insertion of the wound flap in the device, as shown in Figs. 1 and 3. *Le Roy* states that “[w]hen force is applied to the projections [18] they act as levers to spread the longitudinal slit and facilitate the insertion of the wound flap therein.” (*Le Roy*, col. 1, ll. 38-40). *Le Roy* also states that the clip 10 “can be easily and rapidly removed either with applicator 14 or by hand” and that the projections 18 can be squeezed together and act as levers to spread the flanges 28 away from each other, thereby allowing for manual removal of the clip 10. (*Le Roy*, col. 2, ll. 64-67; Fig. 1). Therefore, the intended purpose of *Le Roy*, and the primary focus of its invention, is to include the projections 18 at the proximal end and to allow the projections 18 to be squeezed together so that they act as levers that spread the flanges 28 apart.

Modifying the clip 10 of *Le Roy* to substitute the reversely turned tips 14, 16 located on the distal ends of the arms of *Beaty* for the proximally-located projections 18 of *Le Roy* would render the clip of *Le Roy* unsatisfactory for its intended purpose and would change its principle of operation. The tips 14, 16 of *Beaty* at the distal ends cannot be squeezed together as levers to spread the flanges of the clip apart. Instead, since the tips 14, 16 are located at the distal ends of the arms, the tips 14, 16 would close the clip if squeezed together.

Also, the applicator 14 shown in Fig. 1 of *Le Roy* is only capable of squeezing together two parts, e.g., the projections 18 of *Le Roy* or the tips 14, 16 of *Beaty*. If the clip were modified as proposed by the Office Action, the applicator 14 would merely squeeze the tips 14, 16 of *Beaty* together. If the tips 14, 16 of *Beaty* at the distal ends are squeezed together, the flanges of the clip would be forced toward each other to close the clip. Therefore, the applicator 14 of *Le Roy* would be incapable of opening the modified clip using the tips 14, 16 of *Beaty*. Since the projections 18 of *Le Roy* are intended to be used to open the clip, the proposed modification renders the clip unsatisfactory for its intended purpose and changes its principle of operation.

C. *Le Roy* and *Yoon* do not disclose or suggest the claimed pin, bolt, suture, staple, or rod

Dependent claim 129 recites “an additional anchoring portion including one of a pin, bolt, suture, staple, and rod configured to pierce the tissue fold.” Dependent claim 142 recites similar features. The Office Action contends that the leg sections 24 of *Le Roy* correspond to the claimed additional anchoring portion, and that the leg sections 24 have “a tip that can be called a pin that is capable of piercing tissues.” (Office Action, p. 6, ll. 19-20). However, *Le Roy* states that the leg sections 24 “terminate in flanges 28 . . . [with] parallel undulations 30,” as shown in Figs. 4 and 5, “with blunt or rounded ends 34.” (*Le Roy*, col. 2, ll. 50-60). The sinusoidal undulations 30 of *Le Roy* do not form tips or pins and are not capable of piercing tissue, contrary to the Office Action’s assertion. Rather, *Le Roy* states that the configuration

"minimiz[es] any pain [to the wound flap] or undue damage to the tissue." (*Le Roy*, col. 2, ll. 60-63). *Yoon* does not cure these deficiencies of *Le Roy*, nor was it cited for such disclosure.

D. *Le Roy* and *Yoon* do not disclose or suggest the claimed tapering portion curving away from the gap

Dependent claims 130, 143, and 153 recite that "the distal end of one of the first and second arms includes a tapering portion curving away from the gap." The Office Action appears to contend that *Le Roy* teaches this feature. (Office Action, p. 6, ll. 21-22). The leg sections 24 of *Le Roy*, which the Office Action contends correspond to the claimed arms, include the flanges 28 that are bent inward into the space between the leg sections 24, as shown in Fig. 3 and 5. The flanges 28 of *Le Roy* are curved into the slit 12 separating the flanges 28 so that the flanges 28 taper toward the slit 12. (*Le Roy*, col. 2, ll. 56-60 and Fig. 5). Therefore, even if one were to assume that the leg sections 24 of *Le Roy* correspond to the claimed arms with tapering portions, which Applicant does not concede, *Le Roy* does not disclose that such tapering portions "curv[e] away from the gap," as recited in claims 130, 143, and 153. (Emphasis added). *Yoon* does not cure these deficiencies of *Le Roy*, nor was it cited for such disclosure.

E. *Le Roy* and *Yoon* do not disclose or suggest the claimed barb configured to penetrate a surface of the fold of tissue

Dependent claim 174 recites that "the anchoring portion includes at least a portion in the shape of a barb configured to penetrate a surface of the fold of tissue." Dependent claim 178 recites similar features. The Office Action contends that the flanges 28 of *Le Roy* correspond to the claimed anchoring portion configured to penetrate a surface of the fold of tissue. However, as noted above, the sinusoidal undulations 30 of *Le Roy* formed at the ends of the flanges 28 are not capable of piercing tissue, contrary to the Office Action's assertion. *Yoon* does not cure these deficiencies of *Le Roy*, nor was it cited for such disclosure.

For at least the reasons described above, the rejection of the pending claims includes factual and legal deficiencies with regard to 35 U.S.C. § 103(a) and the M.P.E.P. Applicant requests that the rejection be withdrawn and the claims allowed. Please grant any extensions of time required to enter this response and charge any additional required fee payments to our Deposit Account No. 06-0916.

Respectfully submitted,

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By:



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Dated: March 3, 2009